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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,549	06/01/2000	Marianne E. Greene	ARD7001P0041US	7191

34758 7590 10/22/2003

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EXAMINER

VOGEL, NANCY T

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/587,549	GREENE ET AL.	
	Examiner	Art Unit	
	Nancy Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-11, 16-23 and 25-58 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 16-23, 57 and 58 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-33, 36-46 and 49-56 is/are allowed.
- 6) ☒ Claim(s) 25, 34, 35, 47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 9-11, 16-23, and 25-58 are pending in the case. Claims 9-11, 16-23, 57, and 58 are withdrawn. This action is in reply to applicant's amendment filed 8/11/03.

Election/Restrictions

Applicant's election with traverse of Group VI, claims 25-56, in Paper No. 0803 is acknowledged. The traversal is on the ground(s) that dividing the claims into 7 groups is not warranted and that "this is supported by the Examiner's rationale when discussing the various groups and their similarities". This is not found persuasive because applicants did not point out any specific defects in the Examiner's rationale, and mere number of groups does not constitute an error in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 9-11, 16-23, 57, and 58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 06/1/00.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 USC 112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 66, Number 4, pages 1099-1111). Claim 25 is drawn to a process of screening a substance for its ability to interact with a peroxisome proliferator-activated receptor (PPAR). This is a genus claim in terms of a process of screening a substance for its ability to interact with any peroxisome proliferator-activated receptor. The specification mentions a process of screening a substance for its ability to interact with a human peroxisome proliferator-activated gamma receptor. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claim as one of skill in the art cannot envision all the peroxisome proliferator activated receptors based

on the teachings of the specification. There is no disclosure of the structure of peroxisome proliferator-activated receptors from organisms other than human, or peroxisome proliferator-activated receptors other than the gamma form. While there is some discussion of peroxisome proliferator-activated receptors from xenopus and mouse, there is no disclosure of the precise amino acid sequence of PPAR's from these organisms. There is no detailed structure-function analysis disclosed for the PPAR. Therefore, the specification does not describe the claimed method which comprises providing a peroxisome proliferator-activated receptor polypeptide in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the polypeptides and thus, the method of use of said polypeptides at the time of filing the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 35, 47, 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34, 35, 47 and 48 are vague and indefinite in the recitation of "detected by a reporter gene". The reporter gene cannot detect an interaction between a substance and the receptor polypeptide. Presumably, the interaction is detected by the detection of the production of the polypeptide product encoded by said gene.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Dreyer et al. (Cell Vol. 68, pp. 879-887 (1992)).

Dreyer et al. disclose a method for screening a substance for its ability to interact with a xenopus peroxisome proliferator-activated receptor, said process comprising the steps of : providing a peroxisome proliferator-activated receptor polypeptide, and testing the ability of said substance to interact with said peroxisome proliferator-activated receptor polypeptide (see page 881, second column, line 14 through page 883, first column line 2.)

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Gottlicher et al. (Proc. Natl. Acad. Sci., USA).

Gottlicher et al. disclose a method for screening a substance for its ability to interact with a rat peroxisome proliferator-activated receptor, said process comprising the steps of : providing a peroxisome proliferator-activated receptor polypeptide, and testing the ability of said substance to interact with said peroxisome proliferator-activated receptor polypeptide (see abstract, page 4654, second column, line 12 - page 4656, first column, line 4).

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by Issemann et al. (Nature 347, 645-650 (1990)).

Issemann et al. disclose a method for screening a substance for its ability to interact with a murine peroxisome proliferator-activated receptor, said process comprising the steps of: providing a peroxisome proliferator-activated receptor polypeptide, and testing the ability of said substance to interact with said peroxisome proliferator-activated receptor polypeptide (see page 647, second column, line 5 through page 648 line15).

Claim 25 is rejected under 35 U.S.C. 102(a) as being anticipated by Sher et al. (Biochemistry, Vol. 32, pp. 5598-5604 (1993)).

Sher et al. disclose a method for screening a substance for its ability to interact with a human peroxisome proliferator-activated receptor, said process comprising the steps of : providing a peroxisome proliferator-activated receptor polypeptide, and testing the ability of said substance to interact with said peroxisome proliferator-activated receptor polypeptide (see page 5601 first column line 1- line 18).

Conclusion

Claims 26-33, 36-46, and 49-56 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ntv
10/1/03


TERRY MCKELVEY
PRIMARY EXAMINER